

## **REMARKS**

### **I. STATUS OF THE CLAIMS**

Claims 50-54, 83, 84, 86-91, and 95-99 were under examination at the time of the Action.

Claims 50, 54 and 84 are amended. Support for these amendments can be found at least on pages Thus, claims 50-54, 83, 84, 86-91, and 95-99 are currently under examination.

### **II. REJECTIONS UNDER 35 U.S.C. §112**

#### **A. Written description**

The Action alleges that the current specification lacks written description for contacting the lymphocytes collected on the membrane with a visualization agent and using different wavelength of light and binary masks. Applicants traverse.

The specification provides a section entitled HIV detection starting on page 45. Prior to the HIV detection section is a detailed description of detecting microbes using a membrane based flow system. In particular, the pages 19-21 and 32-35 of the specification describe visualizing a microbe on a membrane and analysis of a membrane using multiple wavelengths of light and binary masks. The teachings of the specification as they relate to microbes is also applied to detection of lymphocytes, particularly page 47, first sentence states “A microporous lymphocyte capture membrane was used in a membrane based flow sensor as previously described.” The particular description relied on in the Action provides an example of the preliminary studies and does not limit the invention to this particular example. For instance, the specification states “For preliminary studies, CD4 cells were purified by immunomagnetic separation from buffy coats obtained from healthy donors. . . “ and for such studies on human subjects “. . . whole blood obtained by venipuncture were incubated with 2 microliters of Alexa488- or Alexa647-conjugated antibodies to CD3, CD4 and/or CD8.” Further support for representative nature of

the microbe examples can be found on page 16 where it is stated “Membrane 110 is selected from a material capable of filtering the analytes of interest from a fluid stream. For example, if microbes represent the analyte of interest, the filter should be capable of removing microbes from a fluid stream.” Thus, microbes are an example of an analyte of interest and the description related to microbes cited above also pertain to other analytes of interest, such as CD4 lymphocytes.

In light of at least these particulars in the specification the current claims are supported by an adequate written description. Applicants request withdrawal of the rejection.

#### **B. Indefiniteness**

The present claims have been amended to address the lack of antecedent basis. The rejection is moot.

#### **III. REJECTION UNDER 35 U.S.C. §103**

Claims 50, 54, 83, 84, 86, 90, 91, and 97-99 are rejected under 35 U.S.C. §103(a) over Law et al. (U.S. Patent 6,709,868) in view of Straus (U.S. publication 2003/0170613). Claims 51-53, 87-89, 95 and 96 are rejected under 35 U.S.C. §103(a) over the ‘868 patent in view of the ‘613 publication in further view of Miller et al. U.S. Patent 3,827,804. Applicants respectfully traverse.

Obviousness requires a suggestion of all the elements in a claim (*CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 [68 USPQ2d 1940] (Fed. Cir. 2003)) and “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 [82 USPQ2d 1385] (2007).

- A. **Claims 50, 54, 83, 84, 86, 90, 91, and 97-99 are rejected under 35 U.S.C. §103(a) over Law et al. (U.S. Patent 6,709,868) in view of Straus (U.S. publication 2003/0170613).**

The current claims are directed to methods that include contacting the lymphocytes collected on the membrane with a visualization agent that can be used to distinguish CD4 positive lymphocytes from other lymphocytes and determining the number of CD4 positive lymphocytes on the membrane. Law et al. does not teach differential labeling and detection of CD4 positive cells. Straus et al. does not remedy the deficiency of Law et al. because the modification of Law et al. would render it unsatisfactory for its intended purpose, i.e., a central aspect to Law is the detection of lymphocytes without using lymphocyte specific antibodies and associated separation methods, see Law et al. Col. 2, lines 45-50, thus replacing the membrane in Law et al with a magnetic separation step renders Law unsatisfactory for its intended purpose. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984))

- B. **Claims 51-53, 87-89, 95 and 96 are rejected under 35 U.S.C. §103(a) over the '868 patent in view of the '613 publication in further view of Miller et al. U.S. Patent 3,827,804.**

Applicants note that if an independent claim is not obvious then claims that depend from the non-obvious claim cannot be obvious because they depend from a nonobvious claim. *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) ("[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious."). Thus, as described above, claim 50 is not obvious therefore those claims that depend from claim 50 are also not obvious.

Applicants request the withdrawal of the rejection.

#### **IV. DOUBLE PATENTING**

Claims 50-54, 83, 84, 86-91, and 95-99 are also provisionally rejected under the doctrine of obviousness-type double patenting. Applicants respectfully ask that the request for a terminal disclaimer be held in abeyance until the present application has been allowed.

#### **V. CONCLUSION**

The present claims are in a condition for allowance and such favorable action is requested. The Examiner is invited to contact the undersigned agent at (512) 536-3167 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



Charles P. Landrum  
Reg. No. 46,855  
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.  
600 Congress Avenue, Suite 2400  
Austin, Texas 78701  
(512) 474-5201  
(512) 536-4598 (facsimile)

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